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Application No. 09/935,173

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant : Henry ISRAEL
Appl. No. : 09/935,173
Filed : 23 August 2001
Title : STENT ASSEMBLY
Group Art Unit: 3731
Examiner : Michael H. Thaler
Docket No. : 1093NES-US
Honorable Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

REMARKS - REQUEST FOR RECONSIDERATION

Applicant has carefully studied the outstanding Official Action mailed on December 17, 2003. This response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

Applicant wishes to express his gratitude to the Examiner for the courtesy of a telephone interview with Applicant's representative David Klein, Patent Agent Reg. No. 41,118. During the interview, the validity of combining Yachia et al. (US Patent 5,246,445) with Pinchuk (US Patent 5,575,818) was discussed.

Claims 1-3, 9, 10 and 13-19 stand rejected under 35 USC §103(a) as being unpatentable over Yachia et al. in view of Pinchuk.

Claims 11-12 stand rejected under 35 USC §103(a) as being unpatentable over Yachia et al. in view of Pinchuk as applied above, and further in view of St. Germain (US Patent 5,836,966).

Applicant respectfully maintains that these rejections are not proper under 35 USC §103(a) and requests reconsideration and allowance of the claims of record.

The basic considerations that apply to obviousness rejections under MPEP §2141 are as follows:

- a) the claimed invention must be considered as a whole;
- b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

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c) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

d) reasonable expectation of success is the standard by which obviousness is determined.

When the prior art itself fails to meet **even one** of the above criteria the cited art does not satisfy 35 USC §103(a) and prevents the establishment of the required *prima facie* case of obviousness by the Examiner. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also In re Rijckaert, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Moreover, to establish the required case of *prima facie* obviousness, the Examiner is required to demonstrate that the prior art discloses or suggests all the critical elements of the invention, without reference to applicants' specification, and that the existence of these elements enables one skilled in the art to practice the invention. See In re Vaack, 947 F.2d 488 (Fed. Cir. 1991).

Moreover, if the prior art methodology must be modified in any way to practice the instant invention the prior art citation must *also* render obvious these modifications or provide a reasonable expectation for the successful practice of the invention with the necessary modifications.

It is respectfully suggested that Yachia et al. cannot be combined with Pinchuk under the above guidelines of MPEP §2141, because they fail to suggest the desirability and thus the obviousness of making the combination, as is now explained.

Yachia et al. describes a stent with bulges that bulge radially outwards. In col. 5, lines 7-15, Yachia et al. states that the bulges are essential in anchoring his device: "The bulges of the device are significant in assisting the device to maintain its relative position within a body vessel, channel, or duct. While non-expandable cylindrical devices would tend to reposition themselves due to body movement and/or fluid flow, devices with bulges tend to remain in position or move only slightly. **The pressure exerted radially by the bulges as well the overall radial pressure from the spiral tend to anchor the device within a passageway.**"

Examiner states that the locking rings of Pinchuk can be combined with Yachia et al. by adding the rings to the ends of the configuration of Fig. 2B of Yachia et al.

However, Pinchuk teaches away from using the stent of Yachia et al. In the background, while discussing the "disadvantages [that] are shared by all prior art stents" (col. 3, line 59), Pinchuk discusses "radial load or force" (col. 3, line 62) of stents and states in col. 4, lines 7-21: "This discrepancy in radial force can cause the stent to take on a cigar or football-like shape in a vessel. The ensuing constriction of the ends of the stent can

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subsequently lead to occlusion of the stent, especially in small diameter vessels where any change in cross-sectional area is very significant. Furthermore, when dealing with an aneurysm, a stent cannot be anchored to the walls of a vessel by its body section as the vessel walls are either damaged and thin or missing. Anchoring at the ends would be equally unfeasible in light of the above described discrepancy in radial force and resulting cigar-like shape of the stent. Thus, the prior art stents cannot advantageously be used in those situations where the stent must be locked in a particular position and the walls of the body cavity in which the stent is inserted cannot provide anchoring means."

Pinchuk then describes his solution of locking rings. He states in col. 4, lines 63-65: "As a result of its higher pitch angle, the locking ring has a greater radial force than that of the rest of the stent."

The point of Pinchuk is to use the locking rings to fix the stent to the body duct wall, and to maintain a straight stent and prevent the cigar-like shape, i.e., bulging of the stent. The skilled artisan would learn from Pinchuk that stents which are anchored by a middle bulging portion are to be avoided because "a stent cannot be anchored to the walls of a vessel by its body section as the vessel walls are either damaged and thin or missing". This is diametrically opposed to the teachings of Yachia et al. which teach that the "pressure exerted radially by the bulges as well the overall radial pressure from the spiral tend to anchor the device within a passageway".

It is noted that Yachia et al. contemplates using his device in vessel walls that are damaged. In col. 3, lines 14-17: "Treatment by means of the device of this invention can also be applied to all kinds of urethral stricture caused by other causes, such as infections, inflammations, and trauma." Trauma is defined in the Merriam-Webster English dictionary as "an injury (as a wound) to living tissue", or alternatively, in the Collins English dictionary as "any bodily injury or wound". Thus, Yachia et al. contemplates using his device in vessel walls that are damaged, which is diametrically opposed to the teachings of Pinchuk.

(Applicant wishes to remind the Examiner that during the interview the Examiner was amenable to allowing the case if it could be shown that Yachia et al. suggests using the bulges to anchor the stent to weakened walls. It is respectfully submitted that the above quote succeeds in showing exactly that point.)

Furthermore, Pinchuk teaches away from using cigar shapes in small diameter vessels, as quoted above: "The ensuing constriction of the ends of the stent can subsequently lead to occlusion of the stent, especially in small diameter vessels where any change in cross-sectional area is very significant." The urethra is a small diameter vessel, as Yachia et

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al. frequently states his device is for opening restrictions in the urethra to large diameters. Thus, once again, Pinchuk is diametrically opposed to the teachings of Yachia et al.

Moreover, it is respectfully submitted that any straight section, not just the locking of Pinchuk, cannot be combined with Yachia et al. The reason is that Yachia et al. teaches away from straight section extensions at the ends of his stent. In col. 5 lines 16-24: "At both ends of the spiral 1 there are provided very small hooks, rings, or balls 3. Hooks or rings can result from, for example bending of the free ends of the wire of which the spiral 1 is wound, and balls can be formed from soldering or melting the ends of the wires. The balls will typically have a diameter of from about 0.2 to 5 mm. It is within the scope of the invention that these attachments 3 could also comprise hooks, rings, balls, or similar means affixed to the wire." No straight section locking rings are contemplated.

Thus it is respectfully submitted that the 35 USC §103(a) rejections are not proper. Applicant respectfully requests reconsideration and allowance of the claims of record, and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
DEKEL PATENT LTD.

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I hereby certify that this correspondence is being transmitted by facsimile to 703-872-9303 at the United States Patent and Trademark Office on March 2, 2004.

David Klein, Reg. No. 41,118
(Name of Applicant's Representative)

David Klein
(Signature)